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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/936,726 | 01/02/2002 | Neil Porter | 08364.0025 | 8955 |
| 22852 | 7590 | 02/25/2005 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | WINSTON, RANDALL O | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 1654 |

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/936,726 | PORTER ET AL. | |
| | Examiner | Art Unit | |
| | Randall Winston | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 December 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-57 is/are pending in the application.
 4a) Of the above claim(s) 14-31,33-35 and 50-57 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-13,32 and 36-49 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>0901</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-13, 32 and 36-49 in applicant's election/restriction response of 12/02/2004 is acknowledged. The traversal is based on the grounds that applicant argues that each of the claims of Groups II to V share features recited in claim 1, and the apparatus claims of Group IV contain elements corresponding to the steps of the method claims of Group I.

Applicant argument is not found persuasive because as Examiner explained in the previous restriction requirement of 11/02/2004, the inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1, because PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of each unrelated method of Groups I-V is: each Group's method produces different products (i.e. a biochemical product or a pharmaceutical product or an agrochemical product) utilizing different steps to produce the different products and/or each Group's method produces the same product utilizing different steps to produce the same product as exemplified above. Moreover, Group I-V and Group VI do not share a special feature because Group IV and Group VI are unrelated as an apparatus and a product made. For example, Group I's biochemical product as claimed can be made by another and materially different apparatus of Group VI such as the apparatus in Berson et al. (US 4868123).

For the reasons above, the inventions of Group I-VI do not share a special technique feature. Accordingly, the search for each of the above inventions is not co-

extensive particularly with regard to the literature. Further, the reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious the other group.

The restriction requirement is still deemed proper and its therefore made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite because the claim is missing a correlation step towards the end. It is suggested that application place a correlation step within the claim and/or towards the end of the claim. For example, it is suggested that applicant place claim 2 within claim 1.

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-13 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Shepherd et al. (US 4,145,254).

Applicant claims a method of producing a biochemical comprising the steps of providing a microorganism on a support: positioning said support such that said microorganism has access to a first medium providing conditions for growth of said microorganism (i.e. and controlling delivery of the first medium by regulating pressure, humidity and concentration); separating said microorganism from said first medium; positioning said support such that said microorganism has access to a second medium providing conditions for biosynthesis of said biochemical by said microorganism (i.e. and controlling delivery of the second medium by regulating pressure, humidity and concentration); extracting said biochemical from biomass of said microorganism and separating said biomass (i.e. secondary metabolite) from an extract of product.

Shepherd et al. anticipate the claimed invention because Shepherd et al. teach (see, abstract, column 1 lines 58-68 and column 2 lines 1-22, column 3 lines 38-41) method of producing a biochemical (i.e. orange and/or red pigment) comprising the steps of providing a microorganism (i.e. *Monascus*) on a support: positioning said support such that said microorganism has access to a first medium providing conditions for growth of said microorganism (please note: one of ordinary skill in the art would inherently expect to control delivery of the first medium by regulating pressure, humidity and concentration from the beginning of the fermentation process to the end of the fermentation process); separating said microorganism from said first medium;

positioning said support such that said microorganism has access to a second medium providing conditions for biosynthesis of said biochemical by said microorganism (please note: one of ordinary skill in the art would inherently expect to control delivery of the second medium by regulating pressure, humidity and concentration from the beginning of the fermentation process to the end of the fermentation process); extracting said biochemical from biomass of said microorganism and separating said biomass (i.e. secondary metabolite is orange and/or red pigment) from an extract of product.

Therefore, the reference is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shepherd et al in view of St. Martin et al. (US 5,013,564).

The primary reference is relied upon for the reason discussed above. Shepherd et al. do not expressly teach separating said biochemical includes performing high pressure liquid chromatography on said extract.

St. Martin et al. beneficially teach (see, examples of column 9 lines 39-53) that performing high pressure liquid chromatography on a said extracted product would produce a more purified isolated extracted product. (i.e. such as *Monascus* pigments)

It is obvious to one of ordinary skill in the art at the time the invention was made to modify Shepherd et al. to include the beneficial teaching of St. Martin et al. because the combined teaching would create an improved method of producing a more purified biochemical (i.e. secondary metabolite of an orange and/or red pigment).

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 36-49 are rejected under 35 U.S.C. 103(a) as unpatentable over Hammann (US 4,772,558).

Applicant claims a method of producing a biochemical comprising the steps of inoculating with a microorganism first face of a support means forming a dividing partition defining first and second volumes of a container, said first volume being in communication with the ambient atmosphere via a gas permeable plug; mounting said support means to said container with said first face of the support means exposed to said first volume and isolated from said second volume; supplying to said second volume a first medium providing conditions for growth of said microorganism; allowing access to said first medium by said microorganism; allowing said microorganism to

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grow at the air/first medium interface; ending access of said microorganism to said first medium and separating said microorganism therefrom by removing a portion of the container which contains said first medium; attaching to said container a replacement for said removed portion; supplying to said second volume a second medium providing conditions for biosynthesis of said biochemical by said microorganism; allowing access to said second medium by said microorganism, and allowing said microorganism to secrete said biochemical into said second medium and further the step of extracting said biochemical from said second medium and/or biomass of microorganism and said microorganism be the secondary metabolite of said microorganism wherein step of separating said biochemical includes performing high pressure liquid chromatography on said extract.

Hammann teaches a method comprising the steps of inoculating with a microorganism first face of a support means forming a dividing partition defining first and second volumes of a container; mounting said support means to said container with said first face of the support means exposed to said first volume and isolated from said second volume; supplying to said second volume a first medium providing conditions for growth of said microorganism; allowing access to said first medium by said microorganism; ending access of said microorganism to said first medium; supplying to said second volume a second medium providing conditions for biosynthesis of said biochemical by said microorganism; transferring microorganisms from the first medium to the second medium by allowing access to said second medium; and by allowing said

microorganism into the second medium to grow to intrinsically produce a biochemical by said microorganism within the second medium.

Hammann does not teach the method of producing a biochemical comprising the claimed steps of said first volume being in communication with ambient atmosphere via a gas permeable plug, allowing said microorganism to grow at the air/first medium interface; removing a portion of the container which contains said first medium; attaching to said container a replacement for said removed portion; conditions such as controlling the delivery of the first medium and/or second medium pressure, humidity and concentration and further the step of extracting said biochemical from said second medium and/or biomass of microorganism by separating the biochemical by performing high pressure liquid chromatography on said extract. However based the overall teachings of Hammann, the adjustment of these and other conventional working conditions (e.g. the claimed steps of said first volume being in communication with ambient atmosphere via a gas permeable plug, allowing said microorganism to grow at the air/first medium interface; removing a portion of the container which contains said first medium; attaching to said container a replacement for said removed portion; controlling the delivery of the first medium and/or second medium pressure, humidity and concentration to help produce the desired biochemical product (i.e. a secondary metabolite) and the further step of extracting said biochemical and separating the biochemical by performing high pressure liquid chromatography on said extract), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Coe
2-18-05
SUSAN D COE
PATENT EXAMINER